

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 2000N-1520]

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Certifier R. LEDESMA

**Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency,
Change From "Junior" to "Light"**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends its menstrual tampon labeling regulation to change the current term for tampons that absorb 6 grams (g) and under of fluid. A tampon with absorbency of 6 g or less is currently required to be labeled as "junior". FDA is changing the term "junior" to "light". The term "junior" implies that the tampon is only for younger or teenage women when, in fact, it may be appropriate for women of any age with light menstrual flow. FDA encourages women to use the lowest absorbency tampon appropriate for their flow to help minimize the risk of Toxic Shock Syndrome (TSS). At present, FDA requires standardized terms to be used for the labeling of a menstrual tampon to indicate its particular absorbency. This rule enables women to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. FDA is issuing this final rule under the Federal Food, Drug, and Cosmetic Act (the act) to ensure that labeling of menstrual tampons is not misleading.

DATES: This rule is effective [*insert date 18 months after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 26, 1989 (54 FR 43766), FDA published a final rule which, among other things, amended its menstrual tampon labeling regulation to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: Less than 6, 6 to 9, 9 to 12, and 12 to 15 g of fluid. FDA announced the availability of the term for 15 to 18 g absorbency tampons ("ultra") in the **Federal Register** of October 18, 2000 (65 FR 62317). When commenting on that proposed rule, manufacturers argued that women should use the least absorbent tampon necessary and that the amount of their menstrual flow, not the age or size of a woman, should determine the absorbency of the tampon she should use. FDA is also aware of literature suggesting that, to minimize the risk of TSS, the lowest absorbency of tampon that is effective should be chosen.

II. The Proposed Rule

In the **Federal Register** of October 18, 2000, FDA published a proposed rule to amend its tampon labeling regulation to change the current term for tampons that absorb 6 g and under of fluid. FDA proposed this change because it believes that changing the standard term for this absorbency range from "junior" to "light" will improve consumer understanding of tampons across brands, and it will make it easier for women to adhere to advice in the tampon

labeling about reducing the risk of TSS. The 90-day comment period closed on January 16, 2001. The agency received comments from two tampon manufacturers.

III. Response to Comments

(Comment 1) Both companies supported FDA's proposal to change the absorbency term for tampons that absorb 0 to 6 g of fluid from "junior" to "light". They agreed with the agency's position that this change will reduce the mistaken impression held by many women that the term "junior" means the tampons are intended only for younger or teenage women, rather than referring to the amount of menstrual flow.

Comments from both manufacturers noted that the proposed effective date of 90 days after publication of the final rule in the **Federal Register** would not allow sufficient time for manufacturers to deplete their inventories of existing packaging materials or revise labeling and artwork on retail packages. Both companies recommended the agency allow a 24-month period following publication of the final rule in the **Federal Register** during which tampons that absorb 6 g or less of fluid could be sold with either a "junior" or a "light" designation. One company recommended that only those tampons which have a valid date code within 24 months of publication of the final rule in the **Federal Register** be allowed to carry the "junior" designation.

(Response) Based on available information regarding labeling of these devices, FDA has concluded that 18 months after publication of the final rule should be sufficient for manufacturers to implement the "light" absorbency designation on their product package labeling.

(Comment 2) Comments from the manufacturers also suggested that the change to "light absorbency" in the U.S. tampon labeling regulation will result

in inconsistency with current Canadian tampon labeling requirements. Both companies recommended agency harmonization with the Canadian requirements so that the same tampon absorbency terms are acceptable in both the United States and Canada.

(Response) The agency intends to work with the Canadian device authorities to harmonize required absorbency terms for tampons.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Any small entity that decided to enter the market for this product would incur no additional costs because of this rule, as that entity would already be

required to identify the absorbency ranges of its tampons. Because this rule imposes minimal costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to amend the menstrual tampon labeling regulation changing the current absorbency term “junior” to “light” to improve consumer understanding of tampon absorbency rates. All manufacturers of menstrual tampons with an absorbency range of less than or equal to 6 g will have to change their package labels and any other labeling using the term “junior” in reference to these products. This is a minor label change because it only requires changing one word on the labeling and will not affect label formatting or the space requirements. Manufacturers should incur minor or no incremental costs as a result of this rule because they will have 18 months in which to implement the changes and the change can be incorporated when new labels are ordered. The 18-month implementation period should also allow manufacturers to deplete their current label inventory.

The Small Business Administration (SBA) classifies a medical device entity as “small” if it has fewer than 500 employees. There are about 10 domestic manufacturers that will be affected by this rule, 5 of which meet

SBA's definition of a small entity. Frequent relabeling is a cost of doing business in the consumer health products market. Some companies will be able to incorporate this labeling change at no additional cost when making other voluntary label changes. The incremental cost of a minor label change such as this is between \$600 and \$3,000, depending on the type of packaging and printing method. A manufacturer will incur this cost for each individual package size it markets that contains tampons with an absorbency rate of 6 g or less. The incremental cost to relabel is less than 1 percent of the small entities' product revenues. Therefore, the final rule will not have a significant economic impact on small entities.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This rule requires tampon manufacturers to provide specific wording supplied by FDA on their labeling. Such information is not included in the definition of "collection of

information” under the Paperwork Reduction Act regulation (5 CFR 1320.3(c)(3)).

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

■ 1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 2. Section 801.430 is amended by revising the table in paragraph (e)(1) to read as follows:

§ 801.430 User labeling for menstrual tampons.

* * * * *

(e) * * *

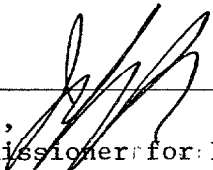
(1) * * *

| Ranges of absorbency in grams ¹ | Corresponding term of absorbency |
|--|----------------------------------|
| 6 and under | Light absorbency |
| 6 to 9 | Regular absorbency |
| 9 to 12 | Super absorbency |
| 12 to 15 | Super plus absorbency |
| 15 to 18 | Ultra absorbency |
| Above 18 | No term |

¹These ranges are defined, respectively, as follows: Less than or equal to 6 grams (g); greater than 6 g up to and including 9 g; greater than 9 g up to and including 12 g; greater than 12 g up to and including 15 g; greater than 15 g up to and including 18 g; and greater than 18 g.

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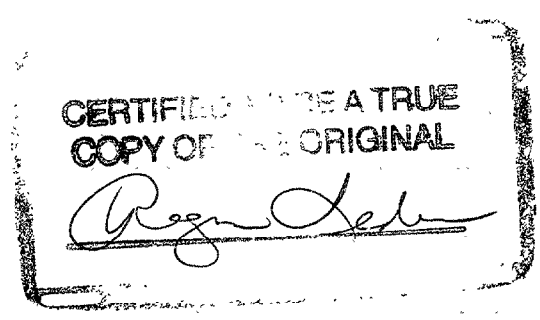
Dated: _____

8/18/04
August 18, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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